DXC 800 (MA) MICROALBUMIN

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PURPOSE

To provide instructions for the quantitative determination of microalbumin on the DXC 800.

PRINCIPLE

MA reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems MA Calibrator, is intended for quantitative determination of Albumin concentration in human urine.

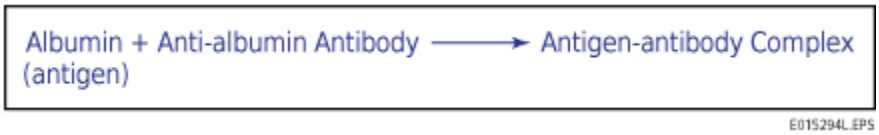
BACKGROUND

Clinical Significance

Measurement of albumin in urine aids in the diagnosis of kidney dysfunction, and is recommended by the American Diabetes Association to screen for microalbuminuria.

Methodology

MA reagent is used to measure the albumin concentration by a turbidimetric method. In the reaction, albumin combines with specific antibody to form insoluble antigen-antibody complexes.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 24 parts reagent. The system monitors the change in absorbance at 380 nanometers. This change in absorbance is proportional to the concentration of albumin in the sample and is used by the System to calculate and express albumin concentration based upon a single-point, non-linear calibration curve.



RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Urine is the only sample type recommended for MA.
Urine samples should be collected without a preservative. The type of sample collection depends on how results are to be reported. If the samples are turbid or contain particulate matter, clarify by centrifugation (3000 x g for 10 minutes).

Specimen Storage and Stability

Urine samples may be stored at +2°C to +8°C for up to 72 hours. Frozen samples are not recommended.

Sample Type	Volume	Sample Stability
Urine	0.5mL	• Centrifuge 3000 xg for 10 min • Room Temp 8 hours • Refrigerated 72 hours • Frozen- Not recommended

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two MA Reagent Cartridges (2 x 100 tests)
One lot-specific Parameter Card

Volume per Test	
Sample Volume	10 µL
Ordac Sample Volume	3 µL
Total Reagent Volume	240 µL
Cartridge Volumes	A 215 µL B 25 µL C – –

Reactive Ingredients	
Reagent Buffer	33.0 mL
MA antibody specific for human albumin (goat)	7.2 mL

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

MA reagent, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent is stable for 60 days unless the expiration date is exceeded. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems MA Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems MA Calibrator is stable until the expiration date printed on the calibrator bottle if capped and stored in the original container at +2°C to +8°C.

Calibration Information

1. The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

2. When starting a new lot of reagent, use the barcode reader on the MC side of the analyzer and scan the parameter card for each barcode in succession.

3. Under typical operating conditions the MA reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

4. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

5. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 controls

STEPS

1. Load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.

2. After reagent load is completed, calibration may be required.

3. Program samples and controls for analysis.

4. After loading samples and controls onto the system, follow the protocols for system operation. At SJMC, the DXC is typically in the automation mode. In order to load samples manually at SJMC, SCH, SFH & SAH see R-W-EQ0900 and R-WEQ0901. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.
Urine samples for MA testing can include 24-hour collections, timed collections, and spot or random collections. Each sample type may require a separate calculation:

24-hour collection:

$$\text{MA result in mg/dL} \times \text{Urine volume, mL} \times \frac{\text{dL}}{\text{100mL}} = \text{mg/24 hours}$$

Timed collection (albumin excretion rate):

$$\text{MA result in mg/dL} \times \text{Urine volume, mL} \times \frac{1}{\text{Time,min.}} \times \frac{\text{1000 µg}}{\text{mg}} \times \frac{\text{dL}}{\text{100 mL}} = \text{µg/minute}$$

Spot collection (albumin/creatinine ratio):

$$\text{MA result in mg/dL} \times \frac{1}{\text{Creatinine, mg/dL}} \times \frac{\text{1000 µg}}{\text{mg}} = \text{µg/mg creatinine}$$

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PERFORMANCE CHARACTERISTICS

Reference Range

Normal	< 30 mg/g Creatinine
Microalbuminuria	30 – 300 mg/g Creatinine
Clinical Albuminuria	> 300 mg/g Creatinine

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Urine	0.2 – 30 mg/dL
Urine (ORDAC)	24 – 97 mg/dL

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

Reporting results outside of analytical range

Lower limit of range: urine	0.2 mg/dL	Result below 0.2, report as <0.2mg/dL
Upper limit of range: urine	97 mg/dL	Results >97 should be diluted, starting at X2, with 0.9% saline, and reanalyzed. Dilute to final result

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for MA determination is 0.2 mg/dL (2.0 mg/L).

LIMITATIONS

1. An effort should be made to keep pipetted samples free from gross debris. It is recommended that highly turbid specimens be centrifuged before analysis.

2. Urine samples contaminated with blood are not recommended.

3. If serum protein carryover is suspected, a saline cup should be assayed prior to analysis of microalbumin samples.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Ascorbic Acid	NA	500 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)
Calcium	NA	130 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)
Citrate	NA	50 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)
Creatinine	NA	160 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)
Glucose	NA	200 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)
Magnesium	NA	400 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)
Oxalate	NA	30 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)
Urea	NA	140 mg/dL	No significant interference (within ± 0.25 mg/dL or 10.8%)

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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